

DEC 12 2000

K003201

510(k) Summary

StealthStation® System - Indications Modification

Date Summary Prepared: October 11, 2000

- I. Company:** Contact: Ronald K. Smith
Medtronic Surgical Navigation Technologies
826 Coal Creek Circle
Louisville, CO 80027
Phone (720) 890-3200
Telefax (720) 890-3500
- II. Product Trade Name:** StealthStation® System with Indications Modification
Common or usual name: Frameless Stereotactic System
Classification name: Stereotactic Instrument (84HAW per 21 CFR 882.4560)
- III.** The above device is substantially equivalent to the StealthStation System cleared multiple 510(k)s, including K954276/K972398/K974187/K992461/K0012844 and to the InstaTrak System, InstaTrak Pediatric System and the InstaTrak 3000 (K960330, K981998 and K983529, respectively).
- IV.** This submission describes a modification to the StealthStation System indications for use to provide additional specific examples of surgical procedures on which use of the StealthStation System may be appropriate.
- V.** The indications for use for the StealthStation System are as follows:

The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model or fluoroscopy images of the anatomy. The StealthStation® System with the ENT option is also indicated for intranasal or sinus use.

Example procedures include, but are not limited to:

Cranial Procedures:

Cranial biopsies.
Tumor resections.
Craniotomies/ Craniectomies.
Skull base procedures.
Thalamotomies/Pallidotomies.
Pituitary Tumor Removal.

CSF leak repair.

Spinal Procedures:

Spinal implant procedures, such as pedicle screw placement.

ENT Procedures:

Transphenoidal procedures.

Intranasal procedures.

Oribital Decompression Procedures.

Optic Nerve Decompression Procedures.

Polyposis procedures

Endoscopic dacryocystorhinostomy

Encephalocele procedures

Sinus procedures, such as Maxillary antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid explorations, Turbinate resections, and Frontal sinusotomies.

- VI.** Since this submission is a change only to the indications for use, the technological characteristics of the device are the same as or similar to those for the predicate StealthStation System. The changes to the indications for use statement are equivalent to the indications for use for the InstaTrak Systems identified as predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 12 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ronald K. Smith
Director, Quality Systems and Regulatory Affairs
Medtronic Surgical Navigation Technologies
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K003201
Trade Name: StealthStation® Treatment Guidance™ Platform
Regulatory Class: II
Product Code: HAW
Dated: October 11, 2000
Received: October 12, 2000

Dear Mr. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

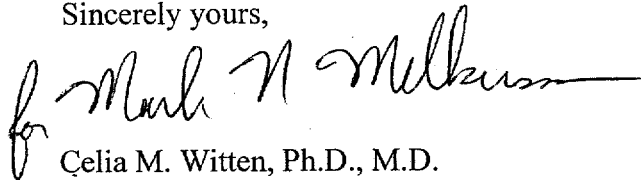
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Ronald K. Smith

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive, flowing style.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003201

Device Name: StealthStation® System – Indications Modification

Indications For Use:

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Encephalocele procedures

Sinus procedures, such as Maxillary antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid explorations, Turbinate resections, and Frontal sinusotomies.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

for Mark N. Milkerson
(Division Sign-Off)

(Optional Format 1-2-96)

Division of General Restorative Devices

510(k) Number K003201-12/00